

REMARKS

Claims 32-50 are pending. Claims 1-31 are canceled. Claims 49 and 50 are withdrawn from consideration. Claims 51-54 are new. Accordingly, claims 32-48 and 51-54 are under consideration. Support for claim 51 is found at least at page 11, lines 16-35. Support for claim 52 is found at least at page 11, lines 32-35. Support for claims 53 and 54 is found at least at page 12, lines 5-11 and Figures 12-14.

Rejections under 35 U.S.C. § 102(b)

Claims 32-45 and 48 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Application No. 2003/0049839 (Romero-Ortega).

The Manual of Patent Examining Procedure (“MPEP”) § 2131 states that, in order to anticipate a claim, a reference must teach every element of the claim:

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1222, 1236, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

MPEP § 2131.

Romero-Ortega disclose a “transparent nerve conduit made of a biodegradable polysaccharide...” for nerve grafting. Page 2, paragraph [0011]. In the prior response, Applicants amended claims 32 and 48 to specify that the epidermal and dermal cells disposed within the lumen are capable of initiating hair follicle neogenesis. As previously indicated, although Romero-Ortega briefly mentions that their scaffolds may be used for tissue engineering of skin, among a list of other possible tissues, Romero-Ortega do not teach a graft comprising epidermal or dermal cells, let alone a graft comprising cells capable of initiating hair follicle neogenesis.

The Examiner appears to assert that the cells present in the scaffolds of Romero-Ortega would inherently comprise epidermal and dermal cells, and inherently would be capable of initiating hair follicle neogenesis, simply by virtue of the fact that they may be skin cells. However, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities.’” MPEP §2112 (IV) citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added).

Applicants respectfully submit that the Office action failed to establish a *prima facie* case of anticipation based on inherency because the Examiner failed to provide a basis in fact and/or technical reasoning to reasonably support the determination that the scaffold conduits of Romero-Ortega are necessarily the same as the claimed invention. Rather than providing basis in fact or technical reasoning, the Examiner asserts that she believes the skin cells disclosed in Romero-Ortega “to be inherently capable of initiating hair follicle neogenesis because the reference does disclose cells for the growth of skin. Skin contains hair follicles, therefore the cells would have to be capable of initiating hair folloicle [sic] neogenesis.” Office action, page 5, lines 5-8. However, the Examiner’s reasoning is flawed, because the growth of skin does not necessarily entail hair follicle neogenesis. Accordingly, simply because skin may grow does not necessarily mean that hair follicle neogenesis will occur, or that the skin cells are inherently capable of hair follicle neogenesis.

Indeed, not only is tissue engineered skin not necessarily capable of initiating hair follicle neogenesis, as noted in the specification of the present application, tissue engineered skin is typically devoid of hair follicles. (Application, page 10, lines 29-32). The Examiner’s statement regarding this disclosure that “limitations from the specification are not read into the claims” (Office action, page 5, lines 12-13) is misguided. The specification is cited, not as guidance for interpreting elements of the claims, but rather as evidence to rebut the Examiner’s contention that tissue engineered skin cells are necessarily capable of initiation hair follicle neogenesis.

In responding to Applicants’ prior argument, the Examiner asserts that the specification merely indicates that tissue engineered skin is “only” typically devoid of hair follicles. In acknowledging that tissue engineered skin typically is devoid of hair follicles, the Examiner appears to be attempting to establish inherency on the basis of possibilities, contrary to established law. As noted above, the Examiner has the burden to establish that the tissue engineered skin of Romero-Ortega is necessarily capable of forming hair follicles. The Examiner has not met this burden.

The Examiner notes that the added language to claims 32 and 48 “does not require hair follicle neogenesis, because the cells only need be capable of neogenesis.” Office action, page 5, lines 8-10. Applicants agree that claims 32 and 48 do not require hair follicle neogenesis. However, the tissue engineered skin cells briefly mentioned by Romero-Ortega would not inherently be capable of hair follicle neogenesis. Applicants attach herewith a Declaration by an inventor of the presently claimed invention, Dr. Thomas Barrows. (the “Declaration”). In the Declaration, Dr. Barrows indicates that “tissue engineered skin cells are not recognized in the art as being inherently capable of hair follicle neogenesis.” (Declaration, part 6). Dr. Barrows indicates that “[t]he hair follicle is a complex structure comprising at least ten different cell types,” that “hair follicle neogenesis is a complex process”, and that “[n]aturally occurring cells within the skin, when cultured, are capable of making new skin but are not capable of making new hair.” (Declaration, part 6). Accordingly, claims 32 and 48 are not anticipated by the disclosure of Romero-Ortega.

Moreover, a *prima facie* case of anticipation has not been established because Romero-Ortega do not teach, either expressly or inherently, a scaffold comprising epidermal and dermal cells, as required by claims 32 and 48. Romero-Ortega disclose merely that their scaffolds may be useful for “the growth of cells for tissue engineering applications including...the growth of skin...” Page 5, paragraph [0053]. The Examiner asserts that the cells present in the scaffolds of Romero-Ortega would inherently comprise epidermal and dermal cells, because the cells are for the tissue engineering of skin. Applicants concede that *in vivo* skin comprises epidermal and dermal cells. However, the use of the scaffolds to grow cells for the growth of skin is not an inherent disclosure that the scaffolds necessarily comprise both dermal and epidermal cells. In the Declaration, Dr. Barrows indicates, for example, that “[s]kin grafts, known as cultured epithelial autografts, may be carried out using cultures containing only epithelial cells.” (Declaration, part 7).

Accordingly, Romero-Ortega do not disclose each and every element of the invention claimed in claims 32 and 48 for at least the reasons discussed above, and claims 32 and 48 are allowable. Because claims 33-45 depend directly or indirectly from claim 32, they are patentable for at least reasons set forth above for claim 32. Allowance of claims 32-45 and 48 is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Romero-Ortega, in view of U.S. Patent Application No. 2003/0090725 (Simpson). The Examiner states that one of ordinary skill in the art would have been motivated to combine the teachings of Romero-Ortega and Simpson to provide a bioabsorbable material having cell attachment binding site moieties as claimed.

“To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Simpson fails to cure the deficiencies of Romero-Ortega discussed above because it also does not teach a graft comprising epidermal and dermal cells, let alone cells capable of initiating hair follicle neogenesis. Thus, neither Romero-Ortega nor Simpson, alone or in combination, teach or suggest all of the limitations of claim 46 and 47, nor would one of skill in the art be motivated to modify their teachings. Accordingly a *prima facie* case of obviousness has not been established.

Claims 46 and 47 depend from allowable claim 32, and accordingly are allowable for at least the reasons set forth above for claim 32. Allowance of claims 46 and 47 is respectfully requested.

New Claims 51-54

New claims 51-54 depend from claim 32, and accordingly are allowable for at least the reasons set forth above for claim 32. In addition, claims 51-54 are allowable for the reasons set forth below.

Claim 51 recites that the dermal and epidermal cells are derived from different sources. Claim 52 recites that the epidermal cells and dermal cells are present in the graft in an amount and proportion sufficient to initiate hair follicle neogenesis. Romero-Ortega and Simpson, taken alone or in combination, do not teach a graft comprising dermal and epidermal cells, let alone make reference to the sources of these cell types, or that such a graft may be used in hair follicle neogenesis. Rather each reference makes only a passing reference to tissue engineering of skin cells, and there is no suggestion or motivation in either reference to obtain dermal and epidermal cells from different sources as required by claim 51, or to have these cells present in an amount and proportion sufficient to initiate hair follicle neogenesis, as required by claim 52.

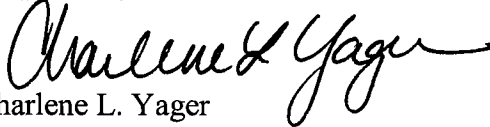
Claim 53 recites that the filament in the graft comprises a first end that is closed, and claim 54 recites that the cells are concentrated at the first end. Neither reference teaches a graft comprising dermal and epidermal cells capable of initiating hair follicle neogenesis concentrated at a first closed end, as required by claim 54.

Allowance of claims 51-54 is respectfully requested.

CONCLUSION

In view of the foregoing it is believed that this application is now in condition for allowance. Should any questions remain, the Examiner is encouraged to contact the undersigned at the number listed below.

Respectfully submitted,


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Attachment: Declaration and Appendix A